IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

TELADOC, INC., *et al*.,	§	
Plaintiffs,	§	
	§	
v.	§	Civil Action No. 1:15-cv-00343-RP
	§	
TEXAS MEDICAL BOARD, *et al*.,	§	
Defendants.	§	

DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS' APPLICATION FOR A TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

TO THE HONORABLE ROBERT PITMAN:

In opposition to the plaintiffs' application for a TRO and preliminary injunction (ECF doc. 10 *et seq*.), the defendants Texas Medical Board ("TMB" or "the Board") and its members in their official capacity only[1] respectfully submit the following response.

[1] By this response the defendants indicated and their counsel do not enter an appearance for the defendant TMB members in their ***individual*** capacity, who as of this writing have not been served. Because the defendants can only comply with injunctive relief "while acting in their official capacity," the preliminary "injunctive relief sought . . . by [plaintiffs] can be obtained from the defendants only in their official capacity as [board members]." *Scott v. Flowers*, 910 F.2d 201, 213 & n. 25 (5th Cir. 1990).

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STANDARDS FOR PRELIMINARY INJUNCTION

"A preliminary injunction is an extraordinary remedy never awarded as of right." *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 24 (U.S. 2008)). "We have cautioned repeatedly that a preliminary injunction is an extraordinary remedy which should not be granted unless the party seeking it has 'clearly carried the burden of persuasion' on all four requirements." *Bluefield Water Ass'n, Inc. v. City of Starkville*, 577 F.3d 250, 253 (5th Cir. 2009). "Generally, a movant must satisfy *each* of four traditional criteria in order to be entitled to a preliminary injunction: (1) irreparable injury, (2) substantial likelihood of success on the merits, (3) a favorable balance of hardships, and (4) no adverse effect on the public interest."[2] *Dennis Melancon, Inc. v. City of New Orleans*, 703 F.3d 262, 268 (5th Cir. 2012) (emphasis original, brackets omitted). "It is not enough for a court considering a request for injunctive relief to ask whether there is a good reason why an injunction should *not* issue; rather, a court must determine that an injunction *should* issue under the traditional four-factor test . . ." *Monsanto Co. v. Geertson Seed Farms*, 561 U.S. 139, 158 (2010) (emphasis original).

FACTS

Pursuant to W.D. TEX. L.R. CV-7(d)(1), the facts pertinent to the issues for preliminary injunction are set out in the accompanying FACTS APPENDIX.

ARGUMENT AND AUTHORITIES AGAINST PRELIMINARY INJUNCTION

Driven by "the haste characteristic of a request for a preliminary injunction," in which "the parties . . . will [not] have . . . the benefit . . . of a full opportunity to present their cases," the present proceedings are not a suitable vehicle for adjudicating the kind of legal issues this suit raises. *See Univ. of Tex. v.*

[2] In most preliminary injunction cases, the likelihood of success on the merits is examined first. *E.g., Ladd v. Livingston*, 777 F.3d 286, 288 (5th Cir.), *cert. denied*, 135 S. Ct. 1197 (2015); *Planned Parenthood Ass'n of Hidalgo Cnty. Tex., Inc. v. Suehs*, 692 F.3d 343, 348 (5th Cir. 2012).

Camenisch, 451 U.S. 390, 395-96 (1981).[3] On the plaintiffs' antitrust claim, for example, "the factfinder must weigh all the circumstances of a case in deciding whether a restricti[on] should be prohibited as imposing an unreasonable restraint on trade," which "can entail a lengthy and laborious process." *Kreuzer v. Am. Acad. of Periodontology*, 735 F.2d 1479, 1490 (D.C. Cir. 1984). Consequently, courts must take care to avoid "the risk of 'premature [invalid]ation of [a regulation] on the basis of factually barebones records.'" *Wash. State Grange v. Wash. State Republican Party*, 552 U.S. 442, 450 (2008).

By addressing the substantive merits of the plaintiffs' claims, the defendants do not waive, and expressly reserve the right to assert, any defenses, affirmative or otherwise, that would defeat the plaintiffs' claims apart from the merits thereof. These include but may not be limited to state action immunity, Eleventh Amendment immunity for TMB to all relief,[4] quasi-judicial and/or quasi-legislative immunity, and qualified immunity for the individual capacity defendants to recovery of damages.[5]

I. The Plaintiffs Cannot Demonstrate A Substantial Likelihood Of Success On The Merits Of Their Claims.

A. The Plaintiffs Cannot Demonstrate a Substantial Likelihood of Success on Their Antitrust Claim.

"To establish a § 1 antitrust violation, a plaintiff must prove '(1) a contract, combination, or conspiracy; (2) that imposed an unreasonable restraint of trade.'" *N. C. State Bd. of Dental Exam'rs v.*

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[3] *See also Zen Music Festivals*, in which the court granted a preliminary injunction holding that the plaintiff had "shown a substantial likelihood" that the challenged statute was unconstitutional but on final judgment found the same statute constitutional and granted summary judgment for the state defendant. *Zen Music Festivals, L.L.C. v. Stewart*, 2002 WL 31106464 (N.D. Tex. 2002), *appeal dism'd as moot*, 2003 WL 21961187 (5th Cir. 2003), *on remand*, 2004 WL 1660452 (N.D. Tex. 2004).

[4] *See Goldfarb v. Va. State Bar*, 421 U.S. 773, 792 n. 22 (1975) ("intimat[ing] no view on the issue" of whether a state bar in "is protected by the Eleventh Amendment" from a Sherman Act suit). *See also Rivera v. Tex. State Bd. of Med. Exam'rs*, 2011 WL 2622648, 431 F. App'x 356, 357 (5th Cir. 2011); *Emory v. Tex. State Bd. of Med. Exam'rs*, 748 F.2d 1023, 1025 (5th Cir. 1984) (because "the Board is a state agency, . . . , the eleventh amendment bars all relief sought against the Board"). The private Teladoc plaintiffs are not in the same position as the FTC suing the North Carolina dental board, *infra*. *E.E.O.C. v. Bd. of Sup'rs for Univ. of La. Sys.*, 559 F.3d 270, 272-73 (5th Cir. 2009) ("the Eleventh Amendment does not shield a State from suit brought by a federal government agency to enforce a federal law").

[5] *See N. C. State Bd. of Dental Exam'rs v. F.T.C.*, 574 U.S. ___, 135 S. Ct. 1101, 1115 (2015) ("this case, which does not present a claim for money damages, does not offer occasion to address the question whether agency officials, including board members, may, under some circumstances, enjoy immunity from damages liability"). *See also Beck v. Tex. State Bd. of Dental Exam'rs*, 204 F.3d 629, 638 (5th Cir. 2000); *Burns-Toole v. Byrne*, 11 F.3d 1270, 1273-74 (5th Cir. 1994).

F.T.C., 717 F.3d 359, 371 (4th Cir. 2013), *aff'd*, 574 U.S. ___, 135 S. Ct. 1101 (2015). Without conceding that the plaintiffs can show the requisite combination or conspiracy,[6] the plaintiffs' claim fails on the second element.

1. The plaintiffs cannot demonstrate a cognizable anticompetitive effect.

"A private plaintiff may not recover damages under § 4 of the Clayton Act merely by showing 'injury causally linked to an illegal presence in the market.'" *Nilavar v. Mercy Health Sys.-W. Ohio*, 494 F. Supp.2d 604, 615 (S.D. Ohio 2005) (citing *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 488 (1977)). "Instead, a plaintiff must prove the existence of '*antitrust* injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.'" *Id*. (emphasis original).

It is well established that the antitrust laws were enacted for "the protection of *competition*, not *competitors*." *Felder's Collision Parts, Inc. v. All Star Adver. Agency, Inc.*, 777 F.3d 756, 757 (5th Cir. 2015) (quoting *Brown Shoe Co. v. U.S.*, 370 U.S. 294, 320 (1962) (emphasis original)).[7] "The elimination of a single competitor, standing alone, does not prove anticompetitive effect." *Abcor Corp. v. AM Int'l, Inc.*, 916 F.2d 924, 931 (4th Cir. 1990) (brackets omitted). Harm to competition must impact consumers, rather than just some competitors. *U.S. v. Microsoft Corp.*, 253 F.3d 34, 58 (D.C. Cir. 2001).

"In proving that a restraint is unreasonable, a plaintiff cannot rely on [its] own economic injury but must show anticompetitive effects that cause[] harm to competition." *Petri v. Va. Bd. of Med.*, 2014 WL 6772478, *2 (E.D. Va. 2014) (citing *Cont'l Airlines, Inc. v. United Airlines, Inc.*, 277 F.3d 499, 508, 515–16 (4th Cir.2002) (quoting *Atl. Richfield Co. v. USA Petroleum Co.*, 495 U.S. 328, 338 (1990))).

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[6] "It is only after concerted action is found that a court need proceed to the second part of the analysis—whether the concerted activity is an unreasonable restraint of trade." *Kreuzer*, 735 F.2d at 1485. "That the challenged conduct of [defend]ants is consistent with legitimate activities . . . weighs against inferring a conspiracy." *Cooper v. Forsyth Cnty. Hosp. Auth., Inc.*, 789 F.2d 278, 282 n. 14 (4th Cir. 1986) (citing *Monsanto Co. v. Spray–Rite Serv. Corp.*, 465 U.S. 752, 762 (1984)).

[7] *Accord Oksanen v. Page Mem'l Hosp.*, 945 F.2d 696, 708 (4th Cir. 1991) (citing *NCAA v. Bd. of Regents*, 468 U.S. 85, 103 (1984)).

Consequently, the disputed regulation would "be unlawful [only] if it foreclosed so much of the market from penetration by [conventional medical practitioners'] competitors[8] as to unreasonably restrain competition in the affected market, the market for [physician] services." *Jefferson Parish Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 30 n. 51 (1984).[9] "To determine whether the [allegedly] anticompetitive [rule] unreasonably restrains competition, the court must analyze 'the competitive significance of the restraint.'" *Petri*, 2014 WL 6772478, *2 (citing *Nat'l Soc'y of Prof'l Eng'rs v. U.S.*, 435 U.S. 679, 692 (1978)).

Among examples of "the kind of injuries that the antitrust laws were enacted to prevent," the relevant items for this case require the plaintiffs to show "that competition regarding the price and quality of physician diagnostic . . . services in the relevant market [will be] suppressed; that patient care in the relevant geographic market [will be] harmed by the lack of competition; that quality assurance and pooling of knowledge [will be] drastically reduced; that patients and referring physicians in the relevant geographic market [will be] deprived of the choice of physician diagnostic . . . service providers; that a *significant* number of consumers of physician diagnostic . . . services [will be] forced to purchase such services from [conventional providers] when they would prefer [telemedicine] physicians; and that patients and referring physicians [will be] deprived of information regarding the quality of physician diagnostic . . . services." *Nilavar*, 494 F. Supp.2d at 617 (emphasis added, numbers omitted). As discussed below, a major purpose of the contested regulation is to prevent harm to patient care by requiring that patients and treating physicians have adequate information to assure quality medical services, whereas the plaintiffs' method of operation results in reduced quality assurance and pooling of knowledge.

[8] Note that members of the TMB are not "competitors" of Teladoc. Telemedicine services are limited to primary care or family practice, not including illnesses requiring treatment with controlled substances or other "life style drugs." No member of the Board practices in primary care or family practice; all are specialists or public members. Exh. 7 at B.

[9] *Partial abrogation in unrelated part on other grounds recognized by Ill. Tool Works Inc. v. Indep. Ink, Inc.*, 547 U.S. 28 (2006) (Congressional amendments to patent statute obviated *Jefferson Parish* holding regarding "tying arrangements").

Teledoc is the only telemedicine provider to oppose the proposed rules in their entirety and to claim that its business would be seriously damaged by their implementation.[10] Other telemedicine providers have thrived, each serving many more patients than Teladoc, in compliance with the procedures required by the rules at issue.[11] Consequently, the withdrawal of the 90 Teladoc contract physicians, due to the company's refusal to operate other than exclusively by telephone with no follow-up or continuity of care, does not "result[] in lower quality services and less choice for consumers and physicians, the types of injuries antitrust laws were enacted to prevent." *Nilavar*, 494 F. Supp.2d at 617. Texas has licensed 70,000 physicians from whom consumers may seek services, including telemedicine.[12]

When given the opportunity to explain to TMB how the proposed rule would impact Teladoc, the plaintiffs provided nothing more than speculation, without concrete data, to support their assertion that the rule would put Teladoc out of business.[13] They did not demonstrated that the additional costs of complying with the rule will result in a total loss of revenue or inability to operate. On the contrary, during the period following the June 16, 2011 letter to Teladoc (doc. 10-1 at 3-5), its revenue reportedly doubled each year.[14]

Any medical practice standard for the protection of patient health and safety imposes additional costs and inconvenience – *e.g.*, medical services could obviously be offered more *cheaply* if physicians did not have to be licensed (with the many years of expensive education and other prerequisites for licensure) or all medications could be dispensed without prescriptions. But it is practicable, nevertheless, to provide telemedicine services profitably within the requirements of the contested rule.[15]

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[10] The 203 comments negative comments (doc. 1 ¶ 10, 115) alleged only harm to Teladoc if the rule were adopted. FACT APPENDIX section 5a ("FACTS § 5a").
[11] Exh. 1 ¶ 4; exh. 2 ¶ 7; FACTS §§ 1, 5a-b.
[12] FACTS § 2.
[13] *Id*. § 5a.
[14] Exh. 27 at 6.
[15] FACTS § 5a.

Teladoc's withdrawal from the market rather than comply with the challenged rules would have no impact on consumer choice among medically underserved populations. Evidence touted by the plaintiffs, the RAND study, shows that most Teladoc users are affluent, live in large urban areas, have access to the traditional health care models, and are using the Teladoc service primarily out of convenience.[16] At least half and probably more of Teladoc users have, or could have, access to primary care physicians, most of whom provide call coverage without charge during nights and weekends.[17]

As a result, the plaintiffs can demonstrate "no anticompetitive effects on the relevant market, nor how the procompetitive benefits of the Board's actions [discussed below] do not justify the potential anticompetitive effects." *Petri*, 2014 WL 6772478, *3. Without a showing that other telemedicine practitioners will fail to join, or will leave, the market as a result of the Board's actions, the plaintiffs have "failed to show the necessary anticompetitive effects of a Sherman Act violation." *Id*. Thus, with "no evidence that the price, the quality, or the supply or demand for" medical services will be "adversely affected by the" regulation at issue, the plaintiffs can make "no showing that the *market as a whole* [will be] affected at all by the" challenged rule. *Jefferson Parish*, 466 U.S. at 31 (emphasis added).

2. The plaintiffs cannot demonstrate an unreasonable restraint on competition.

Assuming for argument that the plaintiffs can show a cognizable restraint of trade at all, they cannot demonstrate that it is unreasonable. "Although the statute speaks in terms of *every* concerted restraint, the courts have long interpreted this language to prohibit only concerted activity which *unreasonably* restrains trade." *Kreuzer*, 735 F.2d at 1485 (emphasis original).

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[16] *Id*. The comments received by the Board from individuals opposing the rule amendments appear to fall in this category. *Id*.

[17] Exh. 9 ¶ 11. In the April 9th hearing, Dr. DePhillips asserted the conclusion, without supporting data, that 50% of Teladoc users do not have primary care physicians. Doc. 10-2 at 135-37. However, the written comments by Teladoc supporters, indicating that the vast majority had PCPs, corroborate the RAND findings as to the demographic makeup of Teladoc patrons. Moreover, individuals using Teladoc who are then referred for follow up care with primary care physicians are actually paying more than they would have if using only primary care physicians providing call coverage. Additionally, those patients receiving poor care as a result of the telephone only consultation will have significantly increased costs related to ongoing care required to deal with the complications or misdiagnosed issues.

a. The plaintiffs' antitrust claim must be analyzed under the "rule of reason."

"In order to prevail in the absence of per se liability,[18] [Teladoc] has the burden of proving that the [rule at issue] violate[s] the Sherman Act because it unreasonably restrain[s] competition," which "necessarily involves an inquiry into the actual effect of the [regulation] on competition among [medical service provider]s." *Jefferson Parish*, 466 U.S. at 29.

The "rule of reason" analysis, which must be utilized in this case,[19] "requires the factfinder to decide whether under all the circumstances of the case the restrictive practice imposes an unreasonable restraint on competition." *N. Tex. Specialty Physicians v. F.T.C.*, 528 F.3d 346, 360 (5th Cir. 2008). In a field posing "significant challenges to informed decisionmaking by the customer for professional services," regulatory "restrictions arguably protecting patients" call for "an enquiry meet for the case, looking to the circumstances, details, and logic of a restraint." *Cal. Dental Ass'n v. F.T.C.*, 526 U.S. 756, 773, 781 (1999). This includes an examination of "facts peculiar to the business to which the restraint is applied; its condition before and after the restraint was imposed; the nature of the restraint and its effect, actual or probable," as well as "the evil believed to exist, the reason for adopting the particular remedy, the purpose or end sought to be attained." *Kreuzer*, 735 F.2d at 1492 (quoting *Chicago Bd. of Trade v. U.S.*, 246 U.S. 231, 238 (1918) (BRANDEIS, J.)).

When a regulation "serves to advance a desirable social goal unrelated to the [regulators'] economic interests," imposing a "requirement [that] improves the quality of care of . . . patients," such

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[18] Courts have recognized three forms of analysis in antitrust cases: (1) *per se*, (2) rule of reason, and (3) "quick look" or abbreviated rule of reason. *N. Tex. Specialty Physicians*, 528 F.3d at 360-62. For the present case, as in most Sherman Act suits, the "rule of reason" is the standard. *Texaco, Inc. v. Dagher*, 547 U.S. 1, 5 (2006) ("[T]his Court presumptively applies rule of reason analysis, under which antitrust plaintiffs must demonstrate that a particular contract or combination is in fact unreasonable and anticompetitive before it will be found unlawful.").

[19] "[W]e have been slow to condemn rules adopted by professional associations as unreasonable *per se*." *F.T.C. v. Ind. Fed'n of Dentists*, 476 U.S. 447, 458 (1986). A state health professional licensing and regulatory board is analogous in important ways, for purposes of antitrust law, to a professional association. *N. C. State Bd. of Dental Exam'rs*, 135 S. Ct. at 1114. Consequently, "rule of reason analysis is appropriate" for Sherman Act challenges to "rules of professional practice which, on their face, establish professional standards of care without reference to the economic interests of the professionals." *Koefoot v. Am. Coll. of Surgeons*, 652 F. Supp. 882, 888 (N.D. Ill. 1986).

that "the rational nexus between the professional rule and public protection" is close, so that "the justification for the [restriction] is closely related to a lawful purpose[,] the rule of reason will generally be satisfied." *Id*. at 1494.

b. The contested regulation's protection of quality patient care is a procompetitive benefit that can outweigh the *de minimis* (if any) restriction on competition.

More than just a commercial transaction is at stake when a member of the public contacts a physician for medical advice. If the advice is wrong, and especially if a prescribed medication is inappropriate for the particular condition involved, more harm may occur than simply a bad financial bargain. Accordingly, antitrust considerations operate somewhat differently for the services of licensed health care professionals than for most business interactions.

"The fact that a restraint operates upon a profession as distinguished from a business is, of course, relevant in determining whether that particular restraint violates the Sherman Act," so that "the public service aspect of a profession may require that a particular practice be treated differently." *N. C. State Bd. of Dental Exam'rs*, 717 F.3d at 375 (quoting *Goldfarb*, 421 U.S. at 788 n. 17) (brackets, ellipse, and internal quotation marks omitted). Thus, restrictions on "certain practices by members of a learned profession might survive scrutiny even though they would be viewed as a violation of the Sherman Act in another context." *Id*. (quoting *Nat'l Soc'y of Prof'l Eng'rs*, 435 U.S. at 686).

"Corrective action against a physician does not violate the antitrust laws if the physician's peer reviewers had legitimate medical reasons to believe that the physician provided substandard care." *Willman v. Heartland Hosp. E.*, 34 F.3d 605, 611 (8th Cir. 1994). Logically, the same deference should apply to state medical regulators mandating or forbidding practices for licensees generally. The rule of reason, then, results in a careful balancing of harms and benefits.

To overcome the considerations that weigh in favor of the defendants, the plaintiffs must demonstrate that the challenged restriction's "purpose or effect is *only* to protect existing health care providers from the competitive threat of potential entrants into or expanders within the same 'market.'" *Hosp. Bldg. Co. v. Trustees of Rex Hosp.*, 691 F.2d 678, 686 (4th Cir. 1982) (emphasis added). To do so, they must show that the defendants' justifications are "so baseless that no reasonable medical practitioner could have reached those conclusions after reviewing the same set of facts." *Willman*, 34 F.3d at 611. The need for the restriction must "be gauged by the fact-finder in relation to the health care needs of the consumer public in the market area at the time in question, objectively assessed." *Hosp. Bldg. Co.*, 691 F.2d at 686.

The circumstances of this case are analogous in critical respects to the facts examined by the Supreme Court in the California Dental Association case. Even more so than with regard to dentist advertising, patients must seek medical service "in a market characterized by striking disparities between the information available to the professional and the patient." *Cal. Dental Ass'n*, 526 U.S. at 771. The Court emphasized "the specialized knowledge required to evaluate the services, and . . . the difficulty in determining whether, and the degree to which, an outcome is attributable to the quality of services . . . or to something else." *Id*. at 772. This factor highlights the danger of relying solely on the patient's own account, without visual contact, direct examination, or access to medical history.

Protecting patient health and safety and improving the quality of patient care are considered ***pro***competitive benefits of state regulation of professional health care services.

> Clearly, a state medical board's authority to monitor and regulate the practice of medicine, and sanction practitioners when necessary, is a market benefit not only for consumers, but for the many practitioners who are willing to stay within the scope of practice created by [state law]. Without such a board, consumers would fall prey to untrained and dangerous practitioners, and well-trained and qualified professionals would lose business and see their profession demeaned.

Petri, 2014 WL 6772478, *3.

The defendants' proposed rule "reflect[s] the prediction that any costs to competition associated with the" requirement of an in-person or face-to-face initial consultation "will be outweighed by gains to consumer information (and hence competition) created by" fully informed, accurate, and appropriate diagnoses, advice, and prescriptions. *Cal. Dental Ass'n*, 526 U.S. at 775.

Such benefits need only even the scales with the anticompetitive effect, so that if the evidence points equally to competitive benefits and detriments, the claim fails. "[A]ntitrust law limits the range of permissible inferences from ambiguous evidence in a § 1 case." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986). "Conduct that is as consistent with a lawful motive as with an unlawful motive, standing alone, does not support the inference of an antitrust conspiracy." *Willman*, 34 F.3d at 611. As shown in the next section, the challenged regulation is *at least as*, indeed *more*, "consistent with the lawful motive of promoting quality patient care as with an anticompetitive motive." *Id.*

c. When the likely benefits are balanced against the likely harms, the challenged regulation is not an unreasonable restraint on competition.

The justifications for the regulation at issue are far more than simply not baseless, but are supported by the judgment of reasonable medical practitioners. The rule allows the patient either of two options: (1) the patient can meet with and be examined by the physician directly in a medical site such as the doctor's office ("in-person") or (2) the patient can communicate with the physician remotely, from an alternate site, including the patient's own home, provided that (a) the physician has diagnostic quality[20] two-way visual as well as audial contact and (b) a medical professional (such as a physician's assistant) is present to insure that vital data is relayed ("face-to-face").[21]

Experienced and knowledgeable physicians, including medical school professors who cannot be said to be in "competition" with the plaintiffs, described to the defendants, in live testimony and by way

[20] *I.e.*, approved by the Federal Trade Commission for the purpose of diagnosis or treatment. Note that mobile phone apps and home computers do not yet fall in this category. *See, e.g.*, exh. 28.
[21] FACTS § 5b.

of written material, the necessity and value of having trained medical personnel physically present with the patient at an initial consultation prior to a physician's prescribing medication for a new condition.[22] There are many visual cues that a patient might not know to mention (or even be aware of) that could be overlooked in consultation exclusively by telephone but which, if known to the physician, would lead to giving different medical advice and/or prescribing different medication.[23] The same is true for diagnostic tests that cannot be performed over the telephone.[24] From witnesses and other sources, the defendants were also made aware of serious negative consequences resulting from the omission of an adequate in-person or face-to-face initial examination.[25]

Teladoc's method of practice also raises related serious concerns pertaining to record-keeping and continuity of care. A physician examining a patient according to standard practice makes notes which then become (manually or electronically) part of the patient's permanent medical record, which will follow her to future locations and can be accessed by future treating personnel.[26] In the Teladoc model, the consumer fills out an online questionnaire and has one telephone conversation with the physician – who, Teladoc admits, cannot even verify that the caller is whom she says she is.[27] The Teladoc physician is unable to review the caller's actual medical records and does not directly enter notes into that record.[28] And by Teladoc policy, the consumer does not consult the same doctor twice.[29] By contrast, the "on-call" providers to whom the plaintiffs seek to compare themselves have direct access to the patient's actual medical record and have an on-going relationship with the patient's (temporarily unavailable) regular

[22] *Id.* § 5a.
[23] *See* evidence cited in FACTS § 5a.
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] FACTS § 1.
[28] *Id.* The Teladoc physician only sends the Teladoc record to the caller's primary care physician if the caller requests it, which only 25-30% do; the notes are entered into the patient's medical record by the primary care physician. *Id.*
[29] *Id.*

physician.[30] Subsequent medical treatment without adequate knowledge of the subject's medical history can lead to serious detrimental results, such that it is a major concern of medical ethics and standards of practice.[31]

On the other side of the scales, the rule is consistent with valid indicia of sound medical practice. The standards of the American Medical Association and the Federation of State Medical Boards call for an initial eyes-on consultation before a new course of treatment is initiated.[32] The Texas Health and Human Services Commission, which "exercise[s] a wide range of governmental powers across different economic spheres, substantially reducing the risk that it would pursue private interests while regulating any single field,"[33] *N. C. State Bd. of Dental Exam'rs*, 135 S. Ct. at 1112-13, has adopted a rule identical to that of the defendants' here for physician services overseen by HHSC.[34]

The Fifth Circuit has held that "Texas's requirement that veterinarians physically examine an animal . . . before treating it (or otherwise practicing veterinary medicine)," which "falls squarely within" a state's "broad power to establish standards for licensing practitioners and regulating the practice of professions," does not violate a practitioner's constitutional free speech, due process, or equal protection rights. *Hines v. Alldredge*, 783 F.3d 197, 201 (5th Cir. 2015). It would be anomalous indeed if antitrust law denied to human patients the protection guaranteed for their pets.

The defendants have chosen "the least restrictive method *available* to achieve the asserted goal." *Kreuzer*, 735 F.2d at 1494 (emphasis added). As shown, the public benefits at stake flow from having an in-person or face-to-face examination precede diagnosis and prescription, while the harms result from the

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[30] *Id.* § 5b.
[31] *See* evidence cited in FACTS § 5a. The plaintiffs' response to the serious risks identified by reputable practitioners based on solid experience is that Teladoc's physicians have not yet been the subject of any malpractice claims by Texas users. However, as the plaintiffs are aware (*see* exh. 11 at B) TMB is currently investigating a number of complaints against Teladoc physicians.
[32] *Id.*
[33] For example, in addition to funding and making rules for health-related services in certain contexts, HHSC also administers the food stamps program and cash assistance payments such as Social Security disability income.
[34] 1 T.A.C. §§ 354.1430-.1432.

omission of the initial examination. Consequently, in the present state of the art, "the least restrictive means of achieving the desired goal," *i.e.*, "the public benefit [that] outweigh[s] the adverse effect on competition," *id*. at 1496, is by requiring the initial examination while allowing remote consultation thereafter.

The amended rules are narrowly tailored to circumscribe telemedicine no more than is reasonably necessary for and beneficial to patient welfare. As shown in the FACT APPENDIX § 5b, (1) only the first visit to establish the patient-physician relationship requires either an in-person or a face-to-face examination with a site presenter -- all subsequent follow-up for up to a year can be done via any method the physician and patient find appropriate; (2) a site presenter is not required for mental health services unless there is a mental emergency; and (3) the telemedicine license allows for interpretation of diagnostic test results without the in-person or face-to-face evaluation.

B. The Plaintiffs Cannot Demonstrate a Substantial Likelihood of Success on Their Interstate Commerce Claim.

The Commerce Clause "protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations." *Exxon Corp. v. Governor of Md.*, 437 U.S. 117, 127-28 (1978). A major purpose is to protect citizens' "right to have access to the markets of other States on equal terms." *Granholm v. Heald*, 544 U.S. 460, 473 (2005). "Almost all health and safety regulations have some incidental effect on commerce." *Operation Badlaw, Inc. v. Licking County Gen. Health Dist. Bd. of Health*, 866 F. Supp. 1059, 1067 (S.D. Ohio 1992) (rejecting Commerce Clause challenge to regulations regarding where one could smoke cigarettes).

"Legislation, in a great variety of ways, may affect commerce and persons engaged in it without constituting a regulation of it, within the meaning of the Constitution." *Huron Portland Cement Co. v. Detroit*, 362 U.S. 440, 442 (1960). "The Commerce Clause was not intended to prohibit states from legislating on subjects relating to the health, life, and safety of their citizens, even though such legislation

may indirectly affect commerce." *Operation Badlaw*, 866 F. Supp. at 1067 (citing *Huron*, 362 U.S. at 442).

Commerce Clause jurisprudence differentiates between state statutes or regulations that "(1) facially discriminate against out-of-state economic interests," and those that "(2) regulate evenhandedly and thereby evince only an indirect burden on interstate commerce." *Dickerson v. Bailey*, 336 F.3d 388, 396 (5th Cir. 2003). "Stated differently, courts ask whether the state statute under review reflects a 'discriminatory purpose' or merely a 'discriminatory effect.'" *Id.* This threshold determination is important because it establishes the constitutional standard of review. If the statute is facially discriminatory, the law is "per se invalid" and the state must show "under rigorous scrutiny, that it has no other means to advance a legitimate local interest." *Id.*

On the other hand, when courts encounter "evenhanded statutes that impose only incidental burdens on interstate commerce," courts engage in the so called *Pike* balancing test. *Id.* (citing *Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970)). Under that analysis, these statutes are "upheld unless the burden imposed on such commerce is clearly excessive in relation to the putative local benefits." *Id.*

Here, the challenged regulation is not facially invalid but, instead, has "only incidental burdens on interstate commerce," if it imposes any at all. *See Dickerson*, 336 F.3d at 396. The rule does not mention out-of-state doctors, patients, or interstate physician-patient transactions. It applies to all Texas licensed physicians who wish to perform telemedicine. It cannot be argued with any credibility that the rule was created to interfere with interstate commerce.

Further, as shown in the FACT APPENDIX and part **I-A** above, the rule does not prohibit a Texas physician, for example, from seeing a patient and then having a telemedicine follow-up phone call while the physician is skiing in Colorado on vacation. Nor does it prohibit a Texarkana physician who works on the Texas side of the border and lives on the Arkansas side from having phone conversations with

patients after she has seen them. Most importantly, **nothing in the contested regulation prevents a physician in a foreign state from performing telemedicine with a patient in Texas**, even if the doctor and patient never meet in-person and the doctor is physically absent from Texas. The rule allows, for example, a New York-based Texas physician to perform telemedicine with a Texas patient so long as the physician can see the patient face-to-face (for example, over Skype or an equivalent video conferencing technology) and the patient is at an established medical site or the patient is accompanied by a professional medical-care provider. Thus, nothing about the regulation at issue interferes with interstate commerce, much less does it facially regulate interstate commerce.

To the extent the Court finds any interference with interstate commerce, such interference is purely incidental to achieving the greater objective of protecting public safety. Teladoc alleges that the rule impinges on interstate commerce because 16 Texas-licensed physicians would allegedly like to prescribe drugs to Texas patients without ever seeing those patients and the rule gets in the way of that by requiring doctors to see patients first. This is purely incidental, just as any health or public safety regulation is likely to incidentally affect interstate commerce. *Operation Badlaw, Inc.*, 866 F. Supp. at 1067 ("Almost all health and safety regulations have some incidental effect on commerce."). Because any interference with interstate commerce is incidental, Teladoc is unlikely to succeed on the merits because any burden imposed on such commerce is outweighed by the benefit of ensuring public safety discussed in the FACT APPENDIX and part **I-A** above—particularly, that doctors physically see patients before prescribing them drugs.

Further, just as the antitrust laws protect competition rather than particular competitors, *see* **I-A-1** above (citing *Brown Shoe*, 370 U.S. at 320), the Commerce Clause "protects the interstate market, not particular interstate firms, from prohibitive or burdensome regulations." *Exxon Corp.*, 437 U.S. at 127-28. Here, nothing about the rule interferes with the ability for telemedicine to happen between patients

and doctors in different states. The plaintiffs' claim is really that *Teladoc* is negatively impacted by the amended regulations, not the citizens of any state, which is the purpose of the Commerce Clause. *See Granholm*, 544 U.S. at 473 (the purpose of the Commerce Clause is to protect citizens' "right to have access to the markets of other States on equal terms.").

II. The Plaintiff Cannot Demonstrate That The Balance Of Equities Favors An Injunction.

Because the plaintiffs cannot demonstrate that they are likely to prevail on the merits, the Court need not reach the remaining three criteria for a preliminary injunction. But if it does, the plaintiffs cannot satisfy the criteria.

The plaintiffs have not shown that they are likely to suffer imminent irreparable injury. They have thus far provided only conclusory assertions, which their economist expert accepts as the premises for his calculations and conclusions, but no concrete data showing the extent of losses they will suffer. They have not provided a plausible estimate of what it would cost them to arrange the initial in-person or face-to-face consultations (such as in cooperation with the employers and health systems through which it covers its subscribers) and what resources it can draw upon to cover the costs. Nor has it provided a data-supported estimate of how much it would have to increase its charges in order to meet the (as yet unspecified) expenses. As shown, other telemedicine providers operating on the same or larger scale as Teladoc have been able to function successfully within the requirements at issue.

The speculative harm to the plaintiffs does not outweigh the damage to the defendants or the disservice to the public interest. An injunction, even limited by its terms to these plaintiffs, will severely disable the Board's ability to protect patients' health, safety, and welfare. Because of the risk of liability to subsequent challengers so long as a federal court ruling is in effect holding the rule in violation of federal law, the TMB out of prudence would have to forebear enforcing the contested regulation against

anyone. Section 190.8(1)(L) does not apply to just telemedicine. If it cannot be enforced, *any* licensee may prescribed drugs for *any*body without laying eyes on the person.

CONCLUSION

In view of all the foregoing, the defendants respectfully urge that the plaintiffs' application for a preliminary injunction be in all things denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing document has been filed electronically with the Court on this the 15th day of May, 2015, which will provide a copy to:

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